July 3, 2007

Diane M. Mandernach
Commissioner
Minnesota Department of Health
P.O. Box 64975
St. Paul, MN 55164-0975

Re: In the Matter of the Proposed Amendments to Rules of the Minnesota Department of Health Governing Newborn Screening, Minnesota Rules, Chapter 4615; Request for Reconsideration of Findings 67 in the Report of the Administrative Law Judge
OAH No. 11-0900-17586-1; Governor's Tracking Number AR232

Dear Commissioner Mandernach,

This matter has come before the Chief Administrative Law Judge for reconsideration pursuant to Minnesota Rules, part 1400.2240, subpart 4. Specifically, the Minnesota Department of Health (MDH) requests that Finding 67 of the ALJ Report be reconsidered.

The report of the ALJ found that Minn. Stat. § 13.386, prohibited MDH's retention and certain uses of blood spots without affirmative parental consent. Finding 67 states in relevant part,

> [T]he newborn screening statute does not expressly authorize the Department to store genetic information indefinitely or disseminate that information to researchers without written informed consent provided by parents. As a result, Minn. Stat. § 13.386 does apply to the proposed rules and the failure to incorporate its requirements into parts 4615.0550 and 4615.0600 constitutes a defect in the rule.

The Department argues that,

> [i]n subdivision 3 of MDH's authorizing statute, Minnesota Statutes, section 144.125, parents have the option of electing to have the tests but to require that all blood samples and records of test results be destroyed within 24 months of the testing. If parents do not exercise this option, the logical conclusion is that the blood samples and test results will be

maintained by MDH. The absence of a time limit in section 144.125 means that the timeframe for storage is indefinite.

The Department is relying on the *implication* that, because the parents have the option to have the blood spots destroyed in 24 months, a parent who does not elect that option is authorizing the Department to retain the blood spots indefinitely.

While one could reasonably draw that inference, Minn. Stat. § 13.386 requires more than a logical inference or implication. It requires the exception to its coverage to be "otherwise *expressly* provided by law." *[Emphasis added.]* An implication or logical inference is not an express provision. There is no express provision in law that exempts the blood spots from the coverage of Minn. Stat. § 13.386.

The Department also contends that if this matter is not reconsidered then it will be unable to comply with the directive in Minn. Stat. § 144.125, subd. 2, to develop new tests in the future. It argues therefore, that Minn. Stat. § 13.386 cannot be read to cover blood spot testing and that section 144.125, subd. 2 is the "express provision" in law.

While requiring written consent for the Department to store blood samples indefinitely may reduce the number of blood spots available for testing, the Department will have all the blood spots of those who do consent available for test development and study. Testing and test development will still be able to continue. Furthermore, the statutory requirement for the development of new tests at best *implies* the need to retain blood spots. It does not expressly exempt retention from section 13.386. There is, therefore, no conflict between Minn. Stat. § 13.386 and Minn. Stat. § 144.125.

Finally, the Department makes several strong policy arguments in favor of its view. The ALJ did not take any position with regard to the importance or value of retention of blood spots. The role of the administrative law judge is not to make policy judgments nor is that a relevant factor for reconsideration.

In view of the above, reconsideration of Finding 67 of the ALJ Report is denied.

Respectfully,

s/Raymond R. Krause

RAYMOND R. KRAUSE
Chief Administrative Law Judge
Minnesota Office of Administrative Hearings

Telephone: (612) 341-7600

RRK:dsc